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OMB No. 0990-0115

Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE http://www.niaid.nih.gov/contract/default.htm FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.

RFP Number:	***Just In Time:***		***Level of Effort:***
NIH-NIAID-DAIT-04-06	[ ] Yes [**X**] No	Small Bus. Set-Aside [ ]Yes [**X**]No 8(a) Set-Aside [ ]Yes [**X**]No NAICS Code: 541710 Size Standard: 500	[ ] Yes [**X**] No ***Total Effort:*** [N/A]

TITLE: Atopic Dermatitis and Vaccinia Network: Clinical Studies Consortium

Issue Date: **April 18, 2003**	***Due Date:*** **July 28, 2003** ***Time:*** **4:00 PM, EST**	***Technical Proposal Page Limits:*** [**X**] Yes *(see "How to Prepare and Submit Electronic Proposals")* [ ] No

ISSUED BY:
Lawrence M. Butler
Senior Contracting Officer
Contract Management Branch, DEA
NIH, NIAID
6700-B Rockledge Drive
Room 2230, MSC 7612
Bethesda, MD 20892-7612

[**X**] ***We reserve the right to make awards without discussion.***

NO. OF AWARDS:
[**X**] Only 1 Award
[ ] Multiple Awards

PERIOD OF PERFORMANCE:
5 years beginning on or about 02/17/2004

Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

POINT OF CONTACT -- **Barry Johnson** --*COLLECT CALLS WILL NOT BE ACCEPTED*--		
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Background
Atopic Dermatitis and Vaccinia Network: Clinical Studies Consortium
RFP-NIH-NIAID-DAIT-04-06

The overall objective of the Atopic Dermatitis and Vaccinia Immunization Network is to develop and implement a research plan to reduce the risk of eczema vaccinatum (EV), a potentially life-threatening complication of vaccinia immunization that occurs almost exclusively in patients with atopic dermatitis (AD). Smallpox (variola) virus is a potential weapon of bioterrorism. Immunization of the population with live vaccinia virus, a species of orthopoxvirus

distinct from variola, may be necessary because it is the only currently available approach to protect against smallpox. Routine smallpox vaccination was terminated in the United States in 1972, and the global eradication of smallpox was achieved in 1980. As a consequence, a large part of the world population today has never been vaccinated against smallpox and does not have immunity to the virus.

Immunization with live vaccinia virus is associated with several serious adverse reactions, and is particularly risky in certain populations such as immunosuppressed individuals. EV is a severe and potentially fatal cutaneous dissemination of vaccinia, with a mortality rate of 10-30% if untreated. The estimated incidence of EV after mass vaccination in the 1960s ranged between 3-80/1,000,000 vaccinees. The incidence of EV after exposure of AD patients to vaccinia is unknown but is probably much higher than the incidence in the general population, in that nearly all cases of EV occur in AD patients, AD patients represented approximately 3-5% of the general population, and only a subset of AD patients were vaccinated or otherwise exposed to vaccinia. The most severe cases were among those who were exposed to vaccinia via a vaccinated contact (e.g., a sibling or parent). The prevalence of AD has increased significantly since the 1960s, so the frequency of EV during a mass vaccination campaign in the 21st century may increase accordingly. Because of the risk for EV, the Department of Health and Human Services, recommends that AD patients avoid contact with recent vaccinees and not receive vaccinia immunization, although such recommendations might change if there were a clearer risk or documented evidence of a bioterrorist attack with smallpox. The current contraindication to exposing AD patients to vaccinia is complicated by the lack of specific biomarkers for detecting AD.

A wide spectrum of virulence factors are encoded by vaccinia and other pox viruses that enable these viruses to evade or neutralize the host immune response. These include homologues of immune receptors, antagonists of chemokines and of complement control proteins, and inhibitors of antiviral enzymes. Therefore, a fully competent immune system may be necessary to counteract these vaccinia-derived immune system antagonists. It is thought that abnormalities in systemic and/or cutaneous immunity are responsible for the susceptibility of AD patients to EV after exposure to vaccinia. AD patients are also susceptible to unusually severe or prolonged infections when exposed to cutaneous viruses other than vaccinia, such as herpes simplex, molluscum contagiosum, papillomaviruses, and varicella. AD patients have been reported to express elevated levels of Th2 cytokines in acute skin lesions, high levels of IgE in blood, and decreased levels of beta-defensins in the skin, suggesting that both the adaptive and innate immune system are impaired in these patients. However, the specific immune abnormalities in AD patients that predispose to susceptibility to severe infections with vaccinia and other cutaneous viruses have not been elucidated.

Immunization of AD patients with live vaccinia is contraindicated because of the risk of EV. The components of the immune system of AD patients relevant to lack of protection from vaccinia can be investigated indirectly, by evaluating AD patients' immune responses to other viruses as surrogates for vaccinia: (a) during natural infections with cutaneous viruses (e.g., herpes simplex), (b) following immunization with highly attenuated, live vaccinia virus (when such viral vaccines are available); and (c) following immunization with certain attenuated, live, FDA-approved viral vaccines.

Animal models of AD will be able to evaluate immune responses not only to surrogate viruses, but also to vaccinia. There are several mouse models of AD including the NC/Nga mouse, the K14-IL-4 transgenic mouse, and the epicutaneously sensitized mouse. These models differ in

skin pathology, genetic and environmental factors required for their development, and immunological abnormalities, and one or more of them may be suitable for in vivo viral challenge studies.

Atopic Dermatitis and Vaccinia Immunization Network:

The Atopic Dermatitis and Vaccinia Immunization Network (hereafter referred to as the "Network") will consist of members supported by three separate contracts to be awarded from the following solicitations:

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RFP NIH-NIAID-DAIT-04-06, entitled "Atopic Dermatitis and Vaccinia Immunization Network (ADVN): Clinical Studies Consortium"

RFP NIH-NIAID-DAIT-04-07, entitled "Atopic Dermatis and Vaccinia Immunization Network (ADVN): Animal Studies Consortium"

RFP NIH-NIAID-DAIT-04-08, entitled "Atopic Dermatitis and Vaccinia Immunization Network (ADVN): Statistical and Data Coordinating Center (SDCC)"

The Network will develop and implement guidelines, policies and procedures regarding conflict of interest on the part of Network-supported investigators, including the disclosure of financial interests relevant to the research to be carried out under this contract, that will enable the Network to meet the requirements for Federally funded research. These guidelines, policies and procedures will be submitted for approval by NIAID. Network-supported investigators will be required to comply with all such policies and procedures.

The Network will require flexibility in expanding, curtailing or discontinuing human and/or animal studies based on changing priorities and scientific opportunities. All such modification in the composition of the Network shall be proposed by the Principal Investigators of each component of the Network after consulting with the Network Executive Committee. These modifications will be reviewed and approved by the Project Officer. As may be appropriate, the NIAID may convene an Expert Panel to provide advice to NIAID on aspects of the Network.

The NIAID will appoint an independent Data and Safety Monitoring Board (DSMB) to advise the Institute on issues under this contract, pertaining to the safety and appropriateness of the protocols and the conduct of the clinical studies, particularly because the Network may carry out studies using investigational agents and also using non-FDA-approved routes of administration of agents (e.g., epidermal administration of certain viral vaccines). The Statistical and Data Coordinating Center will be responsible for all costs associated with this DSMB.

The NIAID will facilitate collaboration and coordination between Network investigators and other current and planned NIAID-supported programs on biodefense and related non-biodefense research.

The NIAID shall review and approve all Network guidelines, policies and procedures.

This REQUEST FOR PROPOSALS (RFP) solicits proposals to establish the Clinical Studies Consortium, which will be a component of the Atopic Dermatitis and Vaccinia Immunization Network. The Clinical Studies Consortium contractor will investigate the immune system in AD patients, and the immune responses of these patients to cutaneous viruses. This information may identify subsets of AD patients who are predisposed to severe viral infections, and should provide important information for the future design of safer and more effective vaccines for AD patients. The tasks to be carried out by the Clinical Studies Consortium will be coordinated with the two other components of the Network: the Animal Studies Consortium and the Statistical and

Data Coordinating Center. The NIAID shall review and approve all activities proposed by the Clinical Studies Consortium.

A broad range of scientific and clinical expertise will be necessary to carry out the requirements of this solicitation. The Government recognizes that no single institution or organization may have the expertise and facilities necessary to perform all requirements. Therefore, the Prime Contractor may have to subcontract portions of the work.

Offerors shall have flexibility in proposing an organizational structure capable of meeting the requirements of this work statement. The Government anticipates that the Clinical Studies Consortium will require strong leadership to provide for the overall scientific direction, coordination and management of research studies and personnel, and requires that there be a single Principal Investigator for the Consortium. Decisions about overall scientific direction, coordination and management of research studies and personnel will be made by the Project Officer in consultation with the Principal Investigator.

STATEMENT OF WORK
ATOPIC DERMATITIS AND VACCINIA IMMUNIZATION NETWORK (ADVN):
CLINICAL STUDIES CONSORTIUM
RFP-NIH-NIAID-DAIT-04-06

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below.

The Contractor shall be responsible for the establishment and management of a Clinical Studies Consortium in support of the Atopic Dermatitis and Vaccinia Immunization Network. The Clinical Studies Consortium is a component of the ADVN, whose purpose is to develop and implement a comprehensive long-term scientific plan to eliminate the risk for eczema vaccinatum or other adverse reactions to vaccinia immunization in patients with atopic dermatitis. The Contractor shall provide the scientific, clinical, technical, and administrative expertise necessary to carry out the tasks specified below and other tasks as directed by the Project Officer.

Specifically, the Contractor shall:

1. **ESTABLISH AND MANAGE A CLINICAL STUDIES CONSORTIUM (a component of the ADVN).**

The Clinical Studies Consortium shall consist of institutions capable of providing the scientific, clinical, technical, leadership and administrative expertise to perform clinical studies in patients with atopic dermatitis.

a. Provide the scientific, clinical, technical, leadership and administrative expertise necessary to carry out the tasks specified below, and other tasks as directed by the Project Officer. The Clinical Studies Consortium, together with the Animal Studies Consortium and the Statistical and Data Coordinating Center, constitute the ADVN.

b. Develop and implement a technical and administrative management and coordination plan for the Clinical Studies Consortium.

c. Chair and participate in the activities of the Network Executive Committee.

d. Design and implement protocols for the conduct of clinical studies on atopic dermatitis patients.

e. Obtain and store blood and tissue samples from atopic dermatitis patients.

f. Identify atopic dermatitis patients for recruitment for a Registry (in collaboration with

the Statistical and Data Coordinating Center of the ADVN).

g. Provide for an orderly transition to a subsequent contractor or the Government, on or before the completion date of this contract.

2. **DEVELOP AND IMPLEMENT A TECHNICAL AND ADMINISTRATIVE MANAGEMENT AND COORDINATION PLAN FOR THE CLINICAL STUDIES CONSORTIUM**

a. The plan shall include processes for:

(1) establishing research priorities;

(2) reviewing, modifying, approving and disapproving proposed studies;

(3) allocating resources;

(4) monitoring and evaluating progress and performance, and redirecting scientific focus and reallocation of resources;

(5) establishing and maintaining effective working relationships and developing partnerships with the pharmaceutical and biotechnology industries to identify the most promising forms of viral vaccines for testing in atopic dermatitis patients; and RFP NIH-NIAID-DAIT-04-06 5

(6) establishing and maintaining effective working relationships with NIAID-sponsored Vaccine and Treatment Evaluation Units and other current and planned NIAID-supported programs on biodefense and

relevant non-biodefense research, to identify the most promising forms of viral vaccines for testing in atopic dermatitis patients, and the most appropriate approaches to study immune and gene expression responses in atopic dermatitis patients.

b. At a minimum, the Clinical Studies Consortium's organizational structure must include the following:

(1) The Clinical Studies Principal Investigator, who will be responsible for the overall leadership, management and coordination of all aspects of the Consortium's activities.

(2) A group of clinical sites, each with a Lead Investigator, to recruit and conduct clinical studies with atopic dermatitis patients.

(3) The scientific and clinical leadership, which shall include: (1) clinical investigators at the clinical sites who have expertise in designing and conducting clinical studies in atopic dermatitis patients, including the effective recruitment and retention of such study populations; (2) immunobiologists with expertise in evaluating adaptive and innate immune responses; (3) vaccinologists; and (4) virologists.

(4) The Clinical Studies Consortium shall participate in a minimum of one 2-day meeting per year, to be held in the Bethesda, Maryland area, in conjunction with one of the Network Executive Committee meetings; and shall conduct monthly conference calls in year 1 of this contract, and a minimum of every two month conference calls in years 2-5 of this contract, or more frequently as may be necessary. These meetings will review the progress of the clinical studies and the technical and administrative coordination plan for the Clinical Studies Consortium.

(5) The Clinical Studies Consortium will chair, and participate in, the Network

Executive Committee. The specific responsibilities for the Network Executive Committee of the Clinical Studies Consortium are described in Statement of Work Paragraph 3. The Network Executive Committee shall have the following organization:

(a) The Network Executive Committee shall be the main governing body of the Network. This Committee is responsible for the conduct and overall activities of the group. The Network Executive Committee provides advice and recommendations to the Principal Investigators of all three components of the Network.

(b) The Clinical Studies Consortium shall propose a governance plan for the Network Executive Committee, which will then be reviewed, modified and approved by the full Executive Committee.

(c) There will be 10 members of the Network Executive Committee. The Project Officer will approve all members of the Network Executive Committee.

1) Chairperson: The Principal Investigator of the Clinical Studies Consortium (voting), who will be responsible for establishing the Network Executive Committee.

2) The Principal Investigator of the Clinical Studies Consortium will choose four other Committee members: two Clinical Studies Consortium Site Leaders and two basic scientists (immunobiologists, vaccinologists, or virologists) (voting).

3) The Principal Investigator of the Animal Studies Consortium will be a member of the Network Executive Committee and will choose one other Committee member from the Animal Studies Consortium -- (Voting)

4) The Principal Investigator of the Statistical and Data Coordinating Center will be a member of the Network Executive Committee, and will choose one other Committee member from the Statistical and Data Coordinating Center -- (Voting)

5) The Project Officer shall be the tenth member of the Committee (non-voting).

(d) The Network Executive Committee will develop operating procedures for the Network, including: (1) the ethical conduct of clinical research involving human subjects; (2) the ethical conduct of animal research; and (3) data analysis, publications and the release of information on Network activities and study findings. The Network Executive Committee may establish separate Subcommittees, including ones that deal with each of the issues described above. RFP NIH-NIAID-DAIT-04-06 6

(e) The Network Executive Committee shall convene three 2-day meetings per year, to be held in the Bethesda, Maryland area, to review governance, operating procedures, progress of ongoing studies, and future plans. This Committee shall also conduct monthly conference calls in year 1 of this contract, and a minimum of bi-monthly conference calls in years 2-5 of this contract, or more frequently as may be necessary. All participant travel and other meeting-associated costs, and all costs associated with the conference calls, will be paid by the Statistical and Data Coordinating Center. Minutes and action items for meetings and conferences of the the Network Executive

Committee and Subcommittees shall be performed by the Statistical and Data Coordinating Center.

3. **CHAIR AND PARTICIPATE IN THE ACTIVITIES OF THE NETWORK EXECUTIVE COMMITTEE**

The Clinical Studies Consortium shall:

a. Provide a governance plan for the Network Executive Committee (as outlined in paragraph 2.b.5.b)

b. Chair, and serve on, the Network Executive Committee and on those subcommittees of the Network Executive Committee that are assigned to the Clinical Studies Consortium.

c. Provide reports about clinical studies planned, implemented, modified, completed or terminated/curtailed; these reports will be supplied to the Statistical and Data Coordinating Center, which will prepare the final version of the reports.

4. **DESIGN AND IMPLEMENT PROTOCOLS FOR THE CONDUCT OF CLINICAL STUDIES ON ATOPIC DERMATITIS PATIENTS**

These protocols represent a plan to address the following scientific objectives:

a. **Assess immune function and gene expression in atopic dermatitis patients**: Develop a protocol to administer a set of assays to evaluate innate and adaptive immunity, and gene expression responses, in vivo or in vitro, to antigens, in atopic dermatitis patients and a control group of individuals without atopic dermatitis. The antigens and assays to be utilized will be finalized within 2 months after the award of the contract.

Patients to be recruited for these and other clinical studies are atopic dermatitis patients without any other known immune abnormality, and appropriate control individuals.

Possible approaches include, but are not limited, to:

(1) Assess immune function in blood and skin biopsies (normal and affected skin)

(2) Assess immune function in blood and skin biopsies after in vitro infection with vaccinia or other viruses.

(3) Evaluate immune and other responses in the subset of atopic dermatitis patients who have either a history of, or currently active, severe cutaneous infections with vaccinia (i.e., eczema vaccinatum) and/or herpes simplex virus (i.e., eczema herpeticum) and/or molluscum contagiosum. These patients will be accessed either by direct recruitment, or from a Registry to be established by a collaboration (see paragraph 6) between the Clinical Studies Consortium and the Statistical and Data Coordinating Center of the Atopic Dermatitis Vaccinia Network.

Assays may include, but are not limited to:

- Gene expression analysis
- Quantitation of epitope-specific T and B cells
- T cell cytokine expression, including an evaluation of Th1 vs. Th2 cytokines
- CTL responses
- Antibody production
- Levels of beta-defensins and other antimicrobials
- Complement function
- NK cell function

b. Assess immune response to live attenuated vaccinia virus: Develop protocols to immunize safely atopic dermatitis patients with experimental, attenuated vaccinia

virus preparations (when such vaccine preparations

are available). It is anticipated that such protocols will be conducted in collaboration with NIAID-supported Vaccine and Treatment Evaluation Units or other NIAID-supported programs, which will take the lead in developing such protocols. The Clinical Studies Consortium will evaluate immunologic and gene expression responses of these atopic dermatitis patients to the attenuated vaccinia viruses, by measurements similar to those described in paragraph 4.a.

Because of safety considerations, initial studies will be with adults.

c. Assess immune response to live attenuated viruses: Develop immunization protocols to immunize safely atopic dermatitis patients with FDA-approved live, attenuated viruses that are surrogates for vaccinia, such as varicella, yellow fever, or other vaccines.

(1) Develop immunization protocols with both standard (subcutaneous) and new (epidermal) routes of vaccine administration.

(2) Utilize such protocols to evaluate immunologic and gene expression responses of atopic dermatitis patients to these viruses, by measurements similar to those described in paragraph 4.a.

Because of safety considerations, initial studies will be with adults.

d. Utilize the results of the studies in paragraphs 4.a, 4.b and 4.c to develop a set of biomarkers to measure the risk of developing eczema vaccinatum in atopic dermatitis patients.

5. **OBTAIN AND STORE BLOOD AND TISSUE SAMPLES FROM ATOPIC DERMATITIS PATIENTS, FOR STUDIES WITHIN THE CLINICAL CONSORTIUM AND FOR STUDIES WITHIN THE ANIMAL STUDIES CONSORTIUM OF THE NETWORK**

The Clinical Studies Consortium shall:

a. Obtain and store blood and tissue samples from patients with atopic dermatitis, and a control group of individuals without atopic dermatitis, and, as needed, provide appropriate handling, storage, shipping, distribution, and quality control of these samples.

b. Assist in collaborative studies with the Animal Studies Consortium of the Network by obtaining and providing

patient blood and tissue samples. Some samples may be used to replace components of the animals' immune

system with human immune cells.

6. **IDENTIFY ATOPIC DERMATITIS PATIENTS FOR RECRUITMENT IN A REGISTRY**

The Statistical and Data Coordinating Center (SDCC) will be responsible for establishing and maintaining a data management system for the Registry. The SDCC will finalize the plan for the Registry within four (4) months after the award of the contract, and begin to enroll patients in the Registry within eight (8) months after the award.

The SDCC will also develop and implement plans for retention and long-term follow-up of patients in the Registry, including telephone interviews of the patients.

The responsibilities of the Clinical Studies Consortium for this Registry are to:

a. Identify and enroll, in a Registry, 200-300 patients with atopic dermatitis and with documented

disseminated vaccinia, and/or disseminated herpes simplex, and/or severe molluscum contagiosum
infection.

b. Prepare appropriate consent forms for patient enrollment.

c. Obtain patient information including: medical history; diagnostic criteria for atopic dermatitis; diagnostic criteria for disseminated vaccinia infection and/or disseminated herpes simplex virus infection and/or persistent and severe molluscum contagiosium infection; dates of infection; treatment and results.

d. Design a questionnaire that will be utilized by the Statistical and Data Coordinating Center for long-term follow-up, including telephone interviews.

7. **PROVIDE FOR AN ORDERLY TRANSITION TO A SUBSEQUENT CONTRACTOR OR THE GOVERNMENT, ON OR BEFORE THE COMPLETION DATE OF THIS CONTRACT:**

Six months prior to the completion date of this contract the Contractor shall submit a transition plan to the NIAID Project Officer for review and approval, including plans for access to all human samples, and all data.

[END OF STATEMENT OF WORK]

NOTES TO OFFERORS
Atopic Dermatitis and Vaccinia Network: Clinical Studies Consortium
RFP-NIH-NIAID-DAIT-04-06

Note 1

For cost-estimating purposes, assume that

• The Clinical Studies Consortium will consist of multiple sites, from 3 to 7

Note 2

• Meetings of the Clinical Studies Consortium will involve two investigators from each of the multiple sites and will take place in Bethesda, MD.

• All participant travel and meeting-associated costs of the Network Executive Committee will be paid for by the Statistical and Data Coordinating Center.

• All computers for data collection compatibility will be purchased by the Statistical and Data Coordinating Center

Note 3

For the tasks described in paragraph 4 of the Statement of Work, the description of this scientific plan should follow the following format:

a. A discussion of state-of-the-art research focused on eliminating the risk of adverse reactions to vaccinia immunization in atopic dermatitis patients;

b. A description of the gaps in current understanding of how to eliminate this risk, and of the scientific opportunities available for developing in vitro and in vivo human studies;

c. A conceptual framework for delineating priorities and the rationale for such priorities;

d. A description of promising in vitro and in vivo human studies, including the rationale for the selection of approaches and the overall study design;

e. A conceptual framework for selecting and designing studies of surrogate markers/biomarkers; and

f. A discussion of implementing this plan in diverse patient populations. It is likely that the

studies in paragraph 4.a will be performed with inclusion of genders, minorities and children. It is also likely that initial studies in paragraphs 4.b and 4.c will be performed in adults with atopic dermatitis; but later studies in paragraphs 4.b and 4.c may, if feasible, be performed with other patient populations, including children and under-served minority patients. The discussion should include protection of human subjects, including children: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm; see subpart D, sections 46.401-46.409.

Note 4

For the tasks described in paragraph 4 of the Statement of Work, for cost estimating purposes, Offerors shall assume that there will be one clinical study initiated in year 1 and one or more clinical studies per year initiated in years 2-5.

Note 5

For the tasks described in paragraph 4.a of the Statement of Work, for cost estimating purposes, Offerors shall assume that:

• 100 control individuals without atopic dermatitis and 200 atopic dermatitis patients without a history of eczema vaccinatum or eczema herpeticum and/or molluscum contagiosum infection will be recruited, and their immune responses evaluated in years 1-2 of the contract.

• Approximately 150 atopic dermatitis patients with a history of eczema vaccinatum and/or eczema herpeticum will be recruited and their immune responses evaluated in years 1-5 of the contract.

• Approximately 75 atopic dermatitis patients with active molluscum contagiosum will be recruited and their immune responses evaluated in years 1-5 of the contract.

For the tasks described in paragraph 4.b of the Statement of Work, for cost estimating purposes, Offerors shall assume that:

• Atopic dermatitis patients will be recruited for immunization protocols in collaboration with NIAID-supported Vaccine and Treatment Evaluation Units or other NIAID-supported programs.

• Samples from 100 atopic dermatitis patients who are immunized with attenuated vaccinia will be obtained for assays of immune response, in years 2-5 of the contract.

For the tasks described in paragraph 4.c of the Statement of Work, for cost estimating purposes, Offerors shall assume that:

• 200 atopic dermatitis patients will be recruited for immunization with live attenuated viral vaccines such as varicella or yellow fever. Immunization will be by both the subcutaneous and epidermal routes. This will occur in years 3-5 of the contract.

It is anticipated that some of the patients recruited for the studies described in paragraphs 4.b and 4.c may be the same as those recruited for the studies described in paragraph 4.a. For cost-estimating purposes, Offerors shall assume that:

• 5% of the patients recruited for the studies in paragraph 4.b are the same as those recruited for the studies in paragraph 4.a, and that 30% of the patients recruited for the studies in paragraph 4.c are the same as those recruited for the studies in paragraph 4.a. Assume that there is no overlap between patients recruited for studies in paragraph 4.b, and those recruited for studies in paragraph 4.c.

Note 6

For the tasks described in paragraph 4.c of the Statement of Work, Offerors shall also include in the Technical Proposal a protocol synopsis for one proposed clinical study with an FDA-approved live attenuated viral vaccine, within the scope of paragraph 4.c. This protocol

synopsis is limited to a maximum of 15 pages.

The protocol synopsis for the clinical study must include the following: (a) A rationale of the study; (b) A summary of basic, pre-clinical and clinical data that supports the pursuit of this protocol; (c) statistical calculations and considerations in determining sample size; (d) study design selected for study, including the dose range(s), timing and route of administration of the virus(es) to be used; (e) criteria for inclusion and exclusion of patients; (f) discussion of risks and benefits; and (g) overview of the outcome measures for safety and clinical response.

Note 7

The Technical Proposal will be limited to 165 pages (which includes the protocol synopsis requested in note 5). In addition, supporting documentation for both the primary contractor and subcontractors (e.g., resumes, relevant publications, Standard Operations Procedures Manuals, use of animals) may be submitted as Appendix material.

Reporting Requirements and Other Deliverables
Atopic Dermatitis and Vaccinia Network: Clinical Studies Consortium
RFP-NIH-NIAID-DAIT-04-06

DELIVERABLES

1. The Contractor shall cooperate with the Animal Studies Consortium and the Statistical and Data Coordinating Center of the ADVN to ensure that all deliverables required for the Network are provided in a timely fashion. The Contractor will provide reports about clinical studies planned, implemented, modified, completed or terminated/curtailed; these reports will be supplied to the Statistical and Data Coordinating center, which will prepare the final version of the reports, for NIAID review and approval.
2. Within sixty (60) days after the award of this contract, the Contractor shall submit an updated plan for clinical studies on atopic dermatitis patients, including the overall design of clinical studies.
3. Beginning in the fourth month of the first year of this contract, the Contractor shall provide updates to clinical studies, including reports about clinical studies planned, implemented, modified, completed or terminated/curtailed; these reports will be supplied to the Statistical and Data Coordinating center, which will prepare the final version of the reports, for NIAID review and approval. Thereafter, updates for clinical studies shall be submitted by the Contractor, for coordination by the Statistical and Data Coordinating Center, three times per year, prior to each Network Executive Committee Meeting, to the NIAID for review and approval.
4. Six months prior to the completion date of this contract, a transition plan including plans for access to all data shall be submitted by the Contractor to the NIAID Project Officer for approval, in order to ensure orderly transition of contract-related material to a successor contractor or the Government.
5. Each year, Annual IRB Approvals shall be delivered by the Contractor to the NIAID Project Officer.
6. Final Deliverable: Final study reports of clinical studies shall be submitted by the Contractor to the Statistical and Data Coordinating Center, and the final coordinated report shall be submitted by the Statistical and Data Coordinating Center.

REPORTING REQUIREMENTS

The Contractor shall submit to the Contracting Officer and to the Project Officer, technical progress reports covering the work accomplished as stated below.

There are five types of required progress reports: (1) an Annual Technical Report, (2) Executive Committee Reports to be provided, along with verbal materials, at each of the Executive Committee meetings, to be held three times each year; (3) Monthly Accrual and Site Registration Reports; (4) Monthly Adverse Event Reports; and (5) a Final Report

All reports shall contain a title page that includes:
Contract number and title
Type of report (Annual, Executive Committee, or Final)
Period of performance being reported
Contractor's name and address
Author(s)
Date of Submission

1. Annual Technical Report

At the completion of each contract year, the Contractor shall submit to the NIAID the Annual Technical Report that summarizes the work accomplished in the preceding twelve month period and outlines work currently in progress. The reports are due on the annual anniversary date of the contract award date. The Annual Technical Report should be factual and concise and consist of the following:

Section I – The scientific agenda for the Network and a brief description of any changes in scientific direction.

Section II – A section that outlines the status of all identified work tasks from the Statement of Work, Attachment A, and provides a brief description of overall progress. The Network is responsible for the following 13 items and any other relevant material. The Contractor must take the lead in material for items 1, and 3, and will provide material for items 5, 11, 12 and 13; and the report incorporating all items will be coordinated by the Statistical and Data Coordinating Center. The 13 items are: (1) clinical studies planned, implemented, modified, completed or terminated/curtailed; (2) animal studies planned, implemented, modified, completed or terminated/curtailed; (3) pertinent interim and final data resulting from clinical studies; (4) pertinent interim and final data resulting from animal studies; (5) status of presentations and publications (6) numbers of patients, in each clinical subset, in the Registry; (7) statistical design considerations; (8) clinical site monitoring and training update; (9) update on distribution of study products; (10) regulatory issues, including the status of INDs; (11) development and modifications of Standard Operating Procedures; (12) policies and procedures developed or revised for the overall management and coordination of the Network; and (13) recommendations for the modification, expansion, curtailment and/or termination of ongoing studies.

Section III – A brief description of all impediments in carrying out the work tasks, whether affecting performance or costs, and recommendations for their resolution.

Section IV – A brief description of tasks to be completed during the next year and of any difficulties anticipated.

2. Executive Committee Reports

The Executive Committee shall meet three times a year. Two (2) weeks in advance of each of the three meetings per year of the Executive Committee, the Network shall be responsible for preparing for the NIAID the following 13 items and any other relevant material. The Contractor must take the lead in material for items 1, and 3, and will

provide material for items 5, 11, 12 and 13; and the report incorporating all items will be coordinated by the Statistical and Data Coordinating Center. The 13 items are: (1) clinical studies planned, implemented, modified, completed or terminated/curtailed; (2) animal studies planned, implemented, modified, completed or terminated/curtailed; (3) pertinent interim and final data resulting from clinical studies; (4) pertinent interim and final data resulting from animal studies; (5) status of presentations and publications (6) numbers of patients, in each clinical subset, in the Registry; (7) statistical design considerations; (8) clinical site monitoring and training update; (9) update on distribution of study products; (10) regulatory issues, including the status of INDs; (11) development and modifications of Standard Operating Procedures; (12) policies and procedures developed or revised for the overall management and coordination of the Network; and (13) recommendations for the modification, expansion, curtailment and/or termination of ongoing studies.

The Contractor shall provide additional verbal progress reports on these topics at the meetings of the Executive Committee for the Network.

3. Monthly Adverse Event Reports

This material will be submitted by the Statistical and Data Coordinating Center, after review by the Contractor: The report shall include all adverse experiences for each open clinical protocol, including copies of adverse experience report forms.

4. Monthly Accrual and Site Registration Reports

This material will be submitted by the Statistical and Data Coordinating Center, after review by the Contractor:

1) For each clinical site enrolling study participants in open clinical protocols: projected overall accrual at each site; date of first enrollment; actual accrual to date; summary of all eligible patients per month and to date; and reasons for non-entry of eligible patients;

2) For each clinical site in the process of registering and obtaining approval to participate in open clinical protocols: outstanding requirements for approval; anticipated date of approval; projected accrual; and any anticipated problems with protocol approval/implementation;

3) Summary of the projected versus actual accrual to date for all approved clinical sites, and reasons for non-entry of eligible patients;

4) For each approved laboratory study associated with an open clinical protocol or animal protocol: status of implementation; status of collection, shipping and receipt of patient samples; problems and/or issues associated with the collection, shipping or receipt of patient samples; and recommendations for resolving any such issues or problems; and

5) Recommendations for modifications in study design, clinical site monitoring, or clinical site training appropriate to improve overall or site-specific accrual, including recommendations for increasing the number of participating clinical sites.

5. Final Technical Report

At the completion of the contract period, the Contractor shall submit the Final Technical Report summarizing the results of the entire contract work for the complete performance period. The Final Report shall be submitted by the expiration date of the contract and shall be submitted in place of the last Annual Report. The Report shall be coordinated and submitted by the Statistical and Data Coordinating Center, and the Clinical Studies Consortium shall provide material to the Statistical and Data Coordinating Center to facilitate this report.

The Final Technical Report shall include: (1) a detailed description of the results of all research conducted under this contract; (2) a scientific agenda to evaluate future research on reducing the

risk of vaccinia immunization in atopic dermatitis patients, including: recommendations for the continuation, expansion or termination of clinical and animal studies undertaken by the Network; recommendations for the overall design of future clinical and animal studies; (3) recommendations for the continuation, expansion or termination of the Registry of patients with atopic dermatitis who have documented disseminated infection with vaccinia virus and/or herpes simplex virus (i.e., eczema vaccinatum and/or eczema herpeticum; and (4) a discussion of problems and obstacles encountered in organizing, managing and coordinating the activities of the Network, methods used to overcome problems and obstacles, and recommendations for improvements.

6. Technical Reports Distribution .

Copies of the technical reports shall be submitted according to the schedule below. If the contractor is unable to deliver the reports specified hereunder within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays, stating the reasons.

Type of Report	No. of Copies	Addressee
Monthly Adverse Event	2	Program Officer
	1	Principal Investigator of Clinical Studies
Monthly Accrual	2	Program Officer
	1	Principal Investigator of Clinical Studies
Executive Committee	2	Program Officer
	1	Contracting Officer Contract Management Branch Division of Extramural Affairs, NIAID National Institutes of Health 6700-B Rockledge Drive Room 2230, MSC 7610 Bethesda, MD 20892-7610
Annual	2	Same as P.O. above
	1	Same as C.O. above
Final	2	Same as P.O. above
	1	Same as C.O. above
Annual IRB Approval	2	Same as P.O. above
	1	Same as C.O. above

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

http://rcb.cancer.gov/rcb-internet/wkf/sample-contract.htm

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL

OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

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ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this URL: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

FAR

Clause No. Date Title

52.202-1 Dec 2001 Definitions

52.203-3 Apr 1984 Gratuities (Over $100,000)

52.203-5 Apr 1984 Covenant Against Contingent Fees (Over $100,000)

52.203-6 Jul 1995 Covenant Against Contingent Fees (Over $100,000)

52.203-7 Jul 1995 Anti-Kickback Procedures (Over $100,000)

52.203-8 Jan 1997 Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)

52.203-10 Jan 1997 Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)

52.203-12 Jun 1997 Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)

52.204-4 Aug 2000 Printing/Copying Double-Sided on Recycled Paper (Over $100,000)

52.209-6 Jul 1995 Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)

52.215-2 Jun 1999 Audit and Records - Negotiation (Over $100,000)

52.215-8 Oct 1997 Order of Precedence – Uniform Contract Format

52.215-10 Oct 1997 Price Reduction for Defective Cost or Pricing Data

52.215-12 Oct 1997 Subcontractor Cost or Pricing Data (Over $500,000)

52.215-14 Oct 1997 Integrity of Unit Prices (Over $100,000)

52.215-15 Dec 1998 Pension Adjustments and Asset Reversions

52.215-18 Oct 1997 Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions

52.215-19 Oct 1997 Notification of Ownership Changes

52.215-21 Oct 1997 Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications

52.216-7 Dec 2002 Allowable Cost and Payment (Paragraph (a) is modified to delete the words Subpart 31.2 and to add the words Subpart 31.3)

52.216-11 Apr 1984 Cost Contract - No Fee RFP NIH-NIAID-DAIT-04-06 17

52.219-8 Oct 2000 Utilization of Small Business Concerns (Over $100,000)

52.219-9 Jan 2002 Small Business Subcontracting Plan (Over $500,000)

52.219-16 Jan 1999 Liquidated Damages - Subcontracting Plan (Over $500,000)

52.222-2 Jul 1990 Payment for Overtime Premium (Over $100,000) (NOTE: The dollar amount in
paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3 Aug 1996 Convict Labor
52.222-26 Apr 2002 Equal Opportunity
52.222-35 Dec 2001 Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era,
and Other Eligible Veterans
52.222-36 Jun 1998 Affirmative Action for Workers with Disabilities
52.222-37 Dec 2001 Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era,
and Other Eligible Veterans
52.223-6 May 2001 Drug-Free Workplace
52.223-14 Oct 2000 Toxic Chemical Release Reporting
52.225-1 May 2002 Buy American Act - Supplies
52.225-13 Jul 2000 Restrictions on Certain Foreign Purchases
52.227-1 Jul 1995 Authorization and Consent, Alternate I (Apr 1984)
52.227-2 Aug 1996 Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11 Jun 1997 Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance
with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in
FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14 Jun 1987 Rights in Data - General, Alternate IV (Jun 1987)
52-232-9 Apr 1984 Limitation on Withholding of Payments
52.232-17 Jun 1996 Interest (Over $100,000)
52.232-20 Apr 1984 Limitation of Cost
52.232-23 Jan 1986 Assignment of Claims
52.232-25 Feb 2002 Prompt Payment
52.232-34 May 1999 Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1 July 2002 Disputes
52.233-3 Aug 1996 Protest After Award, Alternate I (Jun 1985)
52.242-1 Apr 1984 Notice of Intent to Disallow Costs
RFP NIH-NIAID-DAIT-04-06 18
52.242-3 May 2001 Penalties for Unallowable Costs (Over $500,000)

52.242-4 Jan 1997 Certification of Final Indirect Costs
52.242-13 Jul 1995 Bankruptcy (Over $100,000)
52.243-2 Aug 1987 Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2 Aug 1998 Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required,
the identified subcontracts are listed in ARTICLE B.,

Advance Understandings.

52.244-5 Dec 1996 Competition in Subcontracting (Over $100,000)

52.245-5 Jan 1986 Government Property (Cost-Reimbursement, Time and Material, or Labor Hour

Contract)

52.246-23 Feb 1997 Limitation of Liability (Over $100,000)

52.249-5 Sep 1996 Termination for Convenience of the Government (Educational and Other Nonprofit

Institutions)

52.249-6 Sep 1996 Termination (Cost-Reimbursement)

52.249-14 Apr 1984 Excusable Delays

52.253-1 Jan 1991 Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR

Clause No. Date Title

352.202-1 Jan 2001 Definitions - with Alternate paragraph (h) (Jan 2001)

352.228-7 Dec 1991 Insurance - Liability to Third Persons

352.232-9 Apr 1984 Withholding of Contract Payments

352.233-70 Apr 1984 Litigation and Claims

352.242-71 Apr 1984 Final Decisions on Audit Findings

352.249-14 Apr 1984 Excusable Delays

352.270-5 Apr 1984 Key Personnel

352.270-6 Jul 1991 Publication and Publicity

352.270-7 Jan 2001 Paperwork Reduction Act

END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – Rev. 12/2002]

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following clause(s) will be made part of the resultant contract:

FAR Clause 52.216-7, ALLOWABLE COST AND PAYMENT (DECEMBER 2002), is modified in paragraph (a) to delete the words "subpart 31.2 of the Federal Acquisition Regulation (FAR)" and substitute the words "45 CFR part 74, Appendix E".

ALTERNATE II (OCTOBER 2001) of FAR Clause 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN (JANUARY 2002) is added.

FAR Clause 52.232-20, LIMITATION OF COST, is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984) is substituted therefor. **[Note: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

ALTERNATE I (FEBRUARY 2002), of FAR Clause 52.232-25, PROMPT PAYMENT (FEBRUARY 2002) is deleted.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this

solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

FAR 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (JANUARY 1999).

"(c) Waiver of evaluation preference.....

[ ] Offeror elects to waive the evaluation preference."

FAR 52.224-1, Privacy Act Notification (APRIL 1984).

FAR 52.224-2, Privacy Act (APRIL 1984).

Alternate IV (JUNE 1987), FAR 52.227-14, Rights in Data - General (JUNE 1987).

FAR 52.230-5, Cost Accounting Standards - Educational Institution (APRIL 1998).

FAR 52.242-3, Penalties for Unallowable Costs (OCTOBER 1995).

FAR 52.243-2, Changes--Cost Reimbursement (AUGUST 1987), Alternate V (APRIL 1984).

FAR 247-63, Preference for U.S. Flag Air Carriers (JANUARY 1997)`

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION/PUBLIC HEALTH SERVICE ACQUISITION REGULATION (HHSAR)/(PHSAR) (48 CHAPTER 3) CLAUSES:

HHSAR 352.223-70, Safety and Health (JANUARY 2001)

HHSAR 352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities (APRIL 1984).

HHSAR 352.270-8, Protection of Human Subjects (JANUARY 2001).

Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this clause.

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

FAR Clause 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS (MAY 2002)

(a) **Definitions**. As used in this clause--

Commercial item, has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

(c) (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

(i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $500,000 ($1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(ii) 52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).

(iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212(a)).

(iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).

(v) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (JUN 2000) (46 U.S.C. Appx 1241) (flowdown not required for subcontracts awarded beginning May 1, 1996).

(2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: June 28, 2003] (Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

http://www.niaid.nih.gov/contract/ref.htm

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- **TECHNICAL PROPOSAL COVER SHEET**
-

• NIH-1688-1, Project Objectives
• Technical Proposal Cost Information
• Summary of Related Activities
• Optional Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration [When applicable, all institutions must have the form reviewed and approved by their Institutional Review Committee.]
• Government Notice for Handling Proposals
• Targeted/Planned Enrollment Table
• Annual Technical Progress Report Format for Each Study

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

• NIH-2043, Proposal Summary and Data Record
• Small Business Subcontracting Plan Format *[if applicable]*
• Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours
• Offeror's Points of Contact

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

• Inclusion Enrollment Report
• NIH(RC)-1: Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts
• NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts
• NIH-2706: Financial Report of Individual Project Contract
• Instructions for Completing Form NIH-2706
• NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)
• NIH(RC)-11: Research Patient Care Costs
• Safety and Health, HHSAR Clause 352.223-70
• Privacy Act System of Records
• Report of Government Owned, Contractor Held Property
• Government Property – Schedule ___
• Disclosure of Lobbying Activities, OMB Form LLL

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals. *You are required to submit one original paper copy of your proposal along with the number of extra copies required below.*

ELECTRONIC SUBMISSION: In addition to the paper submission, you are requested to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are

identical.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

Shipment and marking of paper copies shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAID-DIAT-04-06

TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original and five (5) unbound copies. Ten (10) copies of all material not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES and CD-Rom or ZipDisk to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Barry Johnson Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Barry Johnson Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 165 PAGES. PAGES THAT AE 2-SIDED WILL COUNT AS 2 PAGES. [THIS PAGE LIMIT INCLUDES: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.]. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

ELECTRONIC SUBMISSION – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON

SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

Formatting Requirements:

• Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.

• Documents must be converted to a .pdf searchable format.

• Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.

• Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.

• Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.

• Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.

• Simplify the color palette used in creating figures.

• Be aware of how large these graphics files become. Large files are discouraged.

• Limit scanned images as much as possible.

• Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF "PROPOSAL INTENT RESPONSE SHEET":

Upon receipt by the Contracting Officer of the "Proposal Intent Response Sheet", offerors will be provided, via e-mail correspondence, specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached "Proposal Intent Response Sheet" by the date provided on that Attachment.

CREATE ADOBE PDF ONLINE -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs $10/month or $100/year. Please link to the following URL for information:

https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE

LOG-IN / TRANSMISSION INSTRUCTIONS:

1. Log-in Site: Will be provided by the Contract Specialist after receipt of the "Proposal Intent Response Sheet"
2. Log-in Name: Will be provided by the Contract Specialist via e-mail.
3. Log-in Password: Will be provided by the Contract Specialist via e-mail.
4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe

Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.

You must have Explorer 3.1 or higher.

It is essential that you use antiviral software to scan all documents.

Click on "Sign On" and enter your log-in name and password.

Click on "Browse" to locate your saved files on your computer.

Click on "Upload Proposal" after you have located the correct file.

After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.

If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.

If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).

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PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIT-04-06

RFP Title: ATOPIC DERMATITIS AND VACCINIA IMMUNIZATION NETWORK (ADVN):

Please review the attached Request for Proposal. Furnish the information requested below and return this page by

.June 27, 2003. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will also be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL

[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____

Address (print): _____

_____

_____

_____

Project Director's Name (print): _____

Title (print): _____

Signature/Date: _____

Telephone Number and E-mail Address (print clearly):

_____

_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____

Title: _____

E-Mail Address: _____
Telephone Number: _____
Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_____
_____
_____
_____

(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH Room 2230 6700-B Rockledge Drive, MSC 7612 Bethesda, MD 20892-7612 Attn: Barry Johnson
RFP-NIH-NIAID- DAIT-04-06 FAX# (301) 402.0972
Email : bjohnson@nih.niaid.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE AND SUBMIT ONE ORIGINAL OF THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT IT AS PART OF YOUR ORIGINAL BUSINESS PROPOSAL. ADDITIONALLY, A COMPLETED ORIGINAL MUST BE SUBMITTED FOR ANY PROPOSED SUBCONTRACTORS.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

a. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision

entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710 .

(2) The small business size standard is 500 employees .

b. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that (ONE AWARD(S)) will be made from this solicitation and that the award(s) will be made on/about February 17, 2004.

It is anticipated that the award(s) from this solicitation will be a multiple-year COST REIMBURSEMENT COMPLETION type contract with a PERIOD OF PERFORMANCE OF 5 years , and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

c. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the total 5-year effort to be approximately 1,940 labor hours.

Estimated Level of Effort	(% Time per Year)	Total % Time
Leadership		
Principal Investigator (1)	25%	25%
Administrative Assistance (1)	50%	50%
Clinical Sites (5)		
Lead Investigator (1)	20%	100%
Project Coordinator (1)	50%	250%
Nurse (1)	50%	250%
Research Assistant (1)	75%	375%
Data Manager (1)	50%	250%
Pharmacist (1)	5%	25%
Registry Recruitment		
Supervisor (1)	30%	30%
Research Assistant (5)	20%	100%

Laboratory Studies-Sites (2)		
Scientist (1)	25%	50%
Research (2)	100%	400%
Sample Distribution		
Supervisor (1)	10%	10%
Administrative (1)	25%	25%

This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

d. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

e. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with the Project Officer or other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

f. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

g. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are [significantly more important than cost or price/approximately equal to cost or price/significantly less important than cost or price]. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

h. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

i. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA, MD 20892-7612 RFP NIH-NIAID-DAIT-04-06 30

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

j. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

k. **USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS**

Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual.

2. INSTRUCTIONS TO OFFERORS

GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a [cost-reimbursement (completion/level of effort)/fixed price] type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J, hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

a. Project Objectives, NIH-1688-1

The Offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

• For an Institution of Higher Education: The form MUST be completed in its entirety.

• For OTHER than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, "INSTRUCTIONS:"

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of

contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS.) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or

instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Human Subjects**

IMPORTANT NOTE TO OFFERORS: The following 6 paragraphs [(9) through (14)] shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (JANUARY 2001)

a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office of Protection from Research Risks (OPRR), National Institutes of Health (NIH), Bethesda, Maryland 20892*****. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR*****, (telephone: 301-496-7014*****), is recommended.

e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR***** an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR*****

and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

f) It is recommended that OPRR***** be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. (End of Provision)

*******Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7014. For more information, the OHRP website may be accessed at http://ohrp.osophs.dhhs.gov/ Copies of the DHHS Regulations for the Protection of Human Subjects, 45 CFR Part 46, are also available on line at* RFP NIH-NIAID-DAIT-04-06 34
http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html.

(10) **Instructions to Offerors Regarding Protection of Human Subjects**

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.
- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be

provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.

- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.

- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.

- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.

- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

(11) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its

technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/ . You may download the information at this site at no cost and modify it, if desired. In addition, the University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

(12) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), ***and applies to research subjects of all ages***.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2)

Epidemiologic and behavioral studies; and (3) Outcomes research and health services research" (http://www.nih.gov/news/crp/97report/execsum.htm).

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table"(see Section J, Attachments)

NOTE 1: *For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at:*
http://www.whitehouse.gov/OMB/fedreg/ombdir15.html
.

NOTE 2: *If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in FAR 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.*

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses,

you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials**[1] require that*:* a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference),

by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form in Section J, Attachments, entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities.

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

[1]See NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, for the Definition of an "NIH-Defined Phase III clinical trial.

Use the format for the Annual Technical Progress Report for Clinical Research Study Populations (See Section J - List of Documents, Exhibits and Other Attachments of the RFP) entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.

(13) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are *clear and compelling* reasons not to include them. **(See examples of Justifications for Exclusion of Children below).** For the purposes of this policy, contracts involving human subjects include categories that would otherwise be

exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors also may obtain copies from the contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The "Human Subjects" section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.
- There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
- The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
- A separate, age-specific study in children is warranted and preferable. Examples include:
- The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or

- The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
- Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different

age-related metabolic processes); or
- Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
- Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
- Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 21 years.

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

(14) **Data and Safety Monitoring in Clinical Trials**

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a

Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the

submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA). Also, in the plan you should describe the frequency of reporting of the conclusions of the monitoring activities. The overall elements of each plan may vary depending on the size and complexity of the trial. The NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.

The frequency of monitoring will depend upon potential risks, complexity, and the nature of the trial; therefore a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual /Safety Officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- Data and Safety Monitoring Board (DSMB - required for multisite trials)
- Institutional Review Board (IRB - required)

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

(15) **Standards for Privacy of Individually Identifiable Health Information**

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply.

Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (http://www.hhs.gov/ocr/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA

Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

(16) **Possession, Use and Transfer of Select Biological Agents or Toxins**

The following notice is applicable when contract performance is expected to involve possession, use and/or transfer of select biological agents or toxins:

Notice to Offerors of Requirements of: 42 CFR Part 73, Select Agents and Toxins (relating to public health and safety**); Agricultural Bioterrorism Protection Act of 2002,** which consists of **7 CFR Part 331, Possession, Use, and Transfer of Biological Agents and Toxins** (relating to plant health or plant products**); and 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins** (relating to human and animal health, animal health or animal products) - **December 13, 2002**

These regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the USA Patriot Act. They are designed to improve the United States Government's ability to prevent, prepare

for, and respond to bioterrorism and other public health emergencies. Unless exempted, entities must receive a certificate of registration or be authorized to work with the applicable select agents as follows:

For possession, use and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to: 1) public health and safety; 2) both human and animal health, animal health, or animal products; and/or 3) plant health or plant products, registration information must be submitted to the Centers for Disease Control and Prevention, Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA) as applicable.

Listings of HHS Select Agents and Toxins, biologic agents and toxins, and Overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/ .

(17) **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf .

(18) **Sharing Research Data**

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. **Therefore, the offeror must submit a plan for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:**

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

**Note to Offeror: If this RFP is for a Multi-Center Clinical Trial or Epidemiological Study, the following paragraph will also apply.*

If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort. RFP NIH-NIAID-DAIT-04-06 42

(19) **Privacy Act (Treatment of Proposal Information)**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:
- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(20) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is this Institute's policy to conduct discussions with all offerors in the competitive range, the Institute reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest

technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The Institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Institute's requirements. Synopses of awards exceeding $25,000 will be published in the FedBizOpps.

(21) **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation [See Section J, Attachments, for an example of such a plan].

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS OR NON-U.S. CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed. RFP NIH-NIAID-DAIT-04-06 44

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

b) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an Attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The

anticipated minimum goals for this RFP are as follows:

23% Small Business

5% Small Disadvantaged Business

3% Women-Owned Small Business
5% HUBZone Small Business
3% Veteran-Owned Small Business
3% Service-Disabled Veteran-Owned Small Business

(22) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(23) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size

The Department of Commerce website for the annual determination is:
http://www.arnet.gov/References/sdbadjustments.htm

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is**

not in any way intended to be a substitute for submission of the subcontracting plan, if it is required by this

solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE		
Targets for SDB Participation - NAICS Industry Subsector 223		
	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

*__NOTE:__ FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(24) **Salary Rate Limitation in Fiscal Year 2003**

NOTE: This award is intended to be made in Fiscal Year 2004. The current Fiscal Year 2003 Salary Rate

Limitations should be adhered to in the preparation of your proposal. All costs associated with any resultant award will be required to be in compliance with the current Fiscal Year 2003 limitations and will be subject to change based on Fiscal Year 2004 Salary Rate Limitations.

Offerors are advised that pursuant to P.L. 108-7, no NIH Fiscal Year 2003 (October 1, 2002 - September 30, 2003) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual

salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I. The salary rate limitation set by P.L. 108-7 applies only to Fiscal Year 2003 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-7 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

LINK TO EXECUTIVE SCHEDULE SALARIES: <http://www.opm.gov/oca/PAYRATES/index.htm > RFP NIH-NIAID-DAIT-04-06 47

(click on "Executive Schedule" for the current Fiscal Year's salary rate or scroll down to the "General Schedule Salary Tables from Previous Years" to locate the Executive Level salary rates from previous years).

(25) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case

of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;

(ii) monitoring of research by independent reviewers;

(iii) modification of the research plan;

(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;

(v) divestiture of significant financial interests; or

(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(26) **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract

funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(27) **Solicitation Provisions Incorporated by Reference**, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

b) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

(28) **Prohibition on Contractor Involvement with Terrorist Activities**

The Offeror/Contractor acknowledges that U. S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance

with these Executive Orders and Laws. This clause must be included in all subcontracts issued under any resultant contract(s).

Office of Health and Safety – Laboratory Registration / Select Agent Transfer Program

The awardee is responsible for ensuring that all work under this grant, cooperative agreement, or contract complies with all Federal requirements related to select agents including CDC's that can be found at http://www.cdc.gov/od/ohs/lrsat.htm and NIH's OBA that can be found at http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html .

TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work

is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES

WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT. RFP NIH-NIAID-DAIT-04-06 51

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Information Other than Cost or Pricing Data

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

[Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

(3) Cost and Pricing Data

1. **General Instructions**

A. You must provide the following information on the first page of your pricing proposal:

(1) Solicitation, contract, and/or modification number;

(2) Name and address of offeror;

(3) Name and telephone number of point of contact;

(4) Name of contract administration office (if available);

(5) Type of contract action (that is, new contract, change order, price

revision/redetermination, letter contract, unpriced order, or other);

(6) Proposed cost; profit or fee; and total;

(7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;

(8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;

(9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;

(10) Date of submission; and

(11) Name, title and signature of authorized representative.

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and

(2) The nature and amount of any contingencies included in the proposed price.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. **Materials and services**. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A.(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) *Adequate Price Competition*. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) *All Other*. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for

establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along

with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

(1) Name and address of licensor.

(2) Date of license agreement.

(3) Patent numbers.

(4) Patent application serial numbers, or other basis on which the royalty is payable.

(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).

(6) Percentage or dollar rate of royalty per unit.

(7) Unit price of contract item.

(8) Number of units.

(9) Total dollar amount of royalties.

(10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

B. **Direct Labor**. Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Indirect Costs**. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. **Other Costs**. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties**. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

F. **Facilities Capital Cost of Money**. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (SECTION J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when

all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of

agreement on price, or an earlier date agreed upon between the parties if applicable.

5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

*****(Please note that data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) shall not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only indicate from what source the proposed costs and prices are substantiated.) *****

(4) Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(5) Other Administrative Data

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).

(2) The offeror's name and remittance address, as stated in the offer.

(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.

(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.

(5) The offeror's account number and the type of account (checking, savings, or lockbox).

(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.

(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

(6) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).
b) What priority the work will be given and how it will relate to other work.
c) The amount of time and facilities available to this project.
d) Information on their cognizant field audit offices.
e) How rights to publications and patents are to be handled.
f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(7) Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(8) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be

completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(9) Travel Costs/Travel Policy

a) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

(10) Certification of Visa's for Non-U.S. Citizens

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its territories, then the offeror must indicate in the proposal that these individuals have the required visas.

SECTION M - EVALUATION FACTORS FOR AWARD
RFP-NIH-NIAID-DAIT-04-06
Atopic Dermatitis and Vaccinia Network: Clinical Studies Consortium

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors, in order of importance, are: technical, cost/price, and Small Disadvantaged Business (SDB) participation. Past performance is NOT an evaluation factor but will be considered in determining an offeror's responsibility in accordance with FAR 9.104-3(b). (Reference Section L.) All evaluation factors other than cost/price, when combined, are significantly more important than cost/price. The trade-off process described in FAR 15.101-1 will be employed. This process permits trade-offs among cost/price and non-cost factors and allows the Government to consider award to other than the lowest priced or highest technically rated offeror. In any event, the Government reserves the right to make an award to that offeror whose proposal provides the best value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be carefully evaluated. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. HUMAN SUBJECT EVALUATION

This research project involves obtaining human subject specimens from Phase I, II and III clinical trials. The offeror(s) are responsible for assuring that the acquisition and supply of human specimen materials (including fetal material) used under this contract were obtained by the Clinical Studies Consortium in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States. [See Federal Regulations at 45 CFR 46 (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm)]

a. **Protection of Human Subjects from Research Risks**

The offeror's proposal must address the involvement of human subjects and protections

from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NIAID that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal and provide a narrative with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated Unacceptable (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or Acceptable.

If your discussion regarding the protection of human subjects from research risks is rated Unacceptable and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your position during such discussions and in your Final Proposal Revision (FPR). If, after discussions, your proposed plan for the protection of human subjects from research risks is still found Unacceptable, your proposal may not be considered further for award.

b. **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html). The principles of data and safety monitoring require that all biomedical and behavioral clinical trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work and SECTION L in the solicitation, as well as any further technical evaluation criteria in this SECTION M, as applicable, for the solicitations specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will provide a narrative that describes the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated Unacceptable (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or Acceptable.

If the information provided regarding Data and Safety Monitoring is rated Unacceptable and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your plan during such discussions and in your Final Proposal Revision (FPR). If, after discussions, the plan is still considered Unacceptable, your proposal may not be considered further for award.

c. **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect [see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm , Definitions - Significant Difference] by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, **OR**
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), **OR**
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will address the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include: RFP NIH-NIAID-DAIT-04-06 62

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of

the subjects and/or to the purpose of the research.

- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
  - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
  - overriding factors dictate selection of subjects); or
  - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.
- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
  - inclusion of those groups would be inappropriate with respect to their health; or
  - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also address whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated Unacceptable (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or Acceptable. See Section L of the solicitation for the requirements of women/minorities inclusion.

If the information you provide in your proposal regarding the inclusion of women and minorities is rated Unacceptable and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify, or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion/exclusion of women/minorities is still considered Unacceptable by the Government after discussions, your proposal may not be considered further for award.

d. **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them [http://grants.nih.gov/grants/guide/notice-files/not98-024.html].

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' narrative evaluation of the offeror's response to this evaluation criterion, this section of the proposal may be rated Unacceptable (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance wit h NIH policy guidelines) or Acceptable.

If the information provided in your proposal about the inclusion of children is rated Unacceptable and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion of children is still considered Unacceptable by the Government after discussions, your proposal may not be considered further for award.

3. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data, or, if data sharing is not possible, the offeror's documentation of its inability to share research data, shall be assessed for appropriateness and adequacy.

4. SMALL DISADVANTAGED BUSINESS PARTICIPATION FACTORS (SUBJECTIVE ASSESSMENT)

Evaluation of the offeror's Small Disadvantaged Business Participation Plan will be based on information obtained from the plan provided by the offeror (with their business proposal), the realism of the proposal, other relevant information obtained from named SDB concerns, and any information supplied by the offeror concerning problems encountered n SDB participation.

Evaluation of SDB Participation Plans will be a subjective assessment based on a consideration of all relevant facts and circumstances. The government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform as the prime contractor. The assessment of the offeror's SDB Participation Plan will be used as a means of evaluating the relative capability and commitment of the offeror and the other competitors. Thus, an offeror with an exceptional record of participation with SDB concerns may receive a more favorable evaluation than another, whose record is acceptable, even though both may have acceptable technical proposals.

SDB Participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB participation Plan will be influential in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The SDB Participation Plan is a separate requirement from the Small Business Subcontracting Plan.

5. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

WEIGHT

A. TECHNICAL APPROACH Points: 55

1. Management Plan: (20 points)

Effectiveness, suitability and feasibility of the:

a. Proposed procedures for management and coordination of Clinical Studies Consortium, including organizational structure, chain of command, operating procedures, timelines, decision-making processes;

b. proposed procedures for identification of members of the Network Executive Committee, and plan for interactions of the Clinical Studies Consortium with the Executive Committee; RFP NIH-NIAID-DAIT-04-06 64

c. proposed organization for governance of the Network Executive Committee, and functions of committees, that will provide successful management of the Network; and

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d. proposed procedures to manage subcontractors and add, replace or remove scientific and technical subcontractor staff to adapt to new demands or changes in scientific direction.

2. Scientific Plan (25 points):

a. Appropriateness of the identified knowledge gaps and scientific opportunities for research to identify defects in innate immune and/or adaptive immune function and/or gene expression in atopic dermatitis patients, and to eliminate their risk for adverse reactions to vaccinia immunization, including the value of immunization with attenuated viruses. Understanding the role of clinical studies in facilitating the aims of the Atopic Dermatitis Vaccinia Network

b. Rationale for and feasibility of the proposed overall scientific agenda, including conceptual framework and approaches to human studies.

c. Scientific rationale for and feasibility of plans to recruit, for a Registry to be managed by the Statistical and Data Coordinating Center of the Network, 200-300 patients with atopic dermatitis with documented disseminated vaccinia, and/or disseminated herpes simplex, and/or severe molluscum contagiosum infection.

3. Sample Protocol (10 points):

Scientific rationale for and feasibility of a protocol synopsis for a proposed clinical study using an FDA-approved live attenuated viral vaccine in atopic dermatitis patients.

B. PERSONNEL QUALIFICATIONS Points: 35

1. Leadership and Management Staff:

Scientific, clinical, technical and administrative leadership qualifications of the proposed Clinical Studies Consortium, including the documented training, experience, leadership competence, and availability of the Principal Investigator and lead professionals at the clinical sites, in activities of similar scope and complexity.

2. Other Personnel

Documented training and experience, demonstrated competence and availability of other professional, technical and administrative staff, including subcontractor and clinical sites personnel, as needed to perform their roles in the proposed Clinical Studies Consortium. This includes expertise in atopic dermatitis, immunology and host defense, virology of vaccinia and related viruses.

3. Staffing Plan

Adequacy and feasibility of staffing plans for project, including the appropriateness of the time commitments of all staff, the mix of expertises, clarity and appropriateness of assigned roles, back-ups for key staff, and evidence that the proposed staff will function well as a team.

C. FACILITIES AND RESOURCES Points: 10

Documented availability and adequacy of facilities, equipment and resources, including shared resources, necessary to carry out all phases of the proposed project.

TOTAL POINTS 100